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REMARKS

Claim 1 has been amended to include the limitations of claim 2, which has been cancelled and to include the limitations of claim 19 which has also been cancelled. In addition, in step C) this step has been amended to delete the removal of dead eggs since these may not be removed by the method of step C).

Also, a number of claims have been cancelled relating to benzyl alcohol as the aralkyl alcohol and/or lice in favor of newly added independent claim 45 limited to benzyl alcohol and lice. In addition, a number of new claims dependent or ultimately dependent on 45 have been added (claims 46-63).

The specification has been amended to comply with the Examiner's objection to the amendment of the specification in the amendment filed 08/22/05. A new amendment has been submitted showing the cancellation of an unnecessary comma in line 6 of the paragraph, which is the only change made to this paragraph.

On pages 2 and 3 of the Office Action, the Examiner has rejected claims 1-13, 15, 16, 18-36 under 35 U.S.C.112, first paragraph as being nonenabling for any aralkyl alcohol and for any ectoparasite, nit or nymph.

It should first of all be noted that U.S. 5,858,383 has claims directed to ectoparasites broadly, and U.S. 6,793,931 contains claims to formula I compounds (see present claim 8).

It is respectfully submitted that the above issued patents show that enablement exists for both ectoparasites and compounds of formula I (present formula I compounds do include additional compounds not included in the claimed formula I compounds of

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U.S. 6,793,931, but the concept that a generic group of compounds are enabled by the disclosure is shown by the claims of U.S. 6,793,931).

The Examiner contends that the specification does not reasonably provide enablement for any aralkyl alcohol and for any ectoparasite and does not enable one skilled in the art to practice the invention commensurate in scope with the claims.

This contention is respectfully submitted to be incorrect.

First of all, the Federal Circuit held of February 11, 2004 in *Liebel-Flarsheim Co. v. Medrad, Inc* (Fed. Cir. 03-1082), that a feature of an invention described in a patent specification may not be imported as a limitation on a claim simply because that feature is included in the sole embodiment of the invention.

Also, as pointed out by the court in *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971), a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statement contained therein which must be relied on for enabling support. How such teaching is set forth, either by the use of illustrative examples or by broad terminology is of no importance. There is no dispute here that the present claims find literal support in the specification.

It is respectfully submitted that in rejecting the claims under 35 U.S.C. 112, the Examiner is charged with the initial burden of providing a basis upon which to support the conclusion that one having ordinary skill in the art would not have been able to

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ascertain the scope of protection defined by the claims, when reasonably interpreted in light of the specification. See In re Moore 439 F.2d 1232, 169 USPQ 236 (CCPA 1971); In re Hammock, 427 F.2d 1378, 166 USPQ 204 (CCPA 1970). The resolution of this legal question necessarily depends upon the facts of each particular case. Smithkline Diagnostics Inc. V Helen Laboratories Corp.; 859 F.2d 878, 8 USPQ2d (1987); Chicago Pneumatic Tool Co. v Hughes Tool Co.; 97 F.2d 945, 38 USPQ 258 (10th Cir. 1938).

Thus, it is respectfully contended that it was incumbent upon the Examiner to substantiate, by factual evidence or sound scientific reasoning that the enabling disclosure is not commensurate in scope with the claimed invention as a whole or as to any aspect thereof. It is further respectfully contended that the Examiner has clearly failed to meet this burden.

The Examiner has provided no factual evidence nor set forth cogent scientific reasoning establishing that the claimed invention encompasses inoperable embodiments, components, or methods or that it would require under experimentation by the skilled artisan to practice the claimed invention given the present invention. Cf. In re Skriwan, 427 F.2d 801, 116 USPQ 85 (CCPA 1970); In re Angstadt 537 F.2d 498, 190 USPQ 214 (CCPA 1976). As pointed out by the court in Skriwan, claims need not recite factors which would be obvious to one of ordinary skill in the art.

One skilled in the art would understand the term "ectoparasite" and the parasites included within the term. The present methods are directed to the killing of such ectoparasites and their eggs by applying the composition of the invention and leaving them in contact with the ectoparasites and their eggs until they have been killed. Hence,

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those skilled in the art would clearly understand how to carry out the method of the invention with any ectoparasite.

In addition, only those ectoparasites that cause an infestation on animal skin are included, and hence the ectoparasites covered by claim 1 are limited in number.

With respect to monohydric aralkyl alcohols, one skilled in the art would have no problem in understanding what compounds fall within the scope this term, or how to use such compounds in the methods of the invention.

In the present application, it is respectfully contended that it is not apparent why one having ordinary skill in the art would not have been able to ascertain the scope of protection defined by the claims when reasonably interpreted in light of the supporting specification, for the reasons discussed above.

It is also respectfully contended that there is no "reason to doubt the objective truth of the statements contained" in the specification and claims.

Hence, it is respectfully submitted that anyone skilled in this art would know exactly how to carry out the claimed methods, especially in the light of the disclosures including operating Examples in the specification. Substituting another compound for benzyl alcohol would not present any enablement problems, nor would carrying out the claimed methods with an ectoparasite other than lice present any enablement problems.

Withdrawal of the section 112 rejection is respectfully solicited.

The Examiner has rejected claims 1-36 and 39 under 35 USC 103 (a) as being unpatentable over the Lover 4368207 and Bassette 6974584 and Cardin et al 5288483, in view of Pearlman 6303581.

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Before discussing the Examiner's position with respect to these references, it may be helpful to discuss what these references teach and what they don't teach relevant to the presently claimed invention.

With respect to the Lover reference, this reference discloses the testing of a large number of alcohols to obtain a pediculicidal rating (as well as an ovicidal rating).

Table I-III are tables showing the screening of compounds that might be effective against lice, not a disclosure that all screened compounds are effective pediculicides.

Benzyl alcohol was tested at 100% alcohol, 25% solution, and a 15/25/60 mixture. The results obtained for benzyl alcohol show that this was not an effective pediculicide, and nowhere in the reference, including the claims, does the reference contend otherwise.

The Lover reference shows that even at a 100% concentration, it was still only 90% effective, i.e. 10% of the lice were left alive to rapidly reproduce.

In a 25% solution in water it had no effectiveness whatsoever, and in a 15% concentration with 25% isopropanol and 60% water, it was only 5% effective.

It should be noted that in column 5 none of the "typical formulations" contained benzyl alcohol.

See also column 2, lines 8-11 where it states that "accordingly, when both pediculicidal and ovicidal activity is desired, it is preferred to employ an unsubstituted alkyl alcohol having a log p value of 2.13-5.1". Benzyl alcohol and other monohydric aralkyl alcohols are not "unsubstituted aralkyl alcohol(s)", and benzyl alcohol has a p value of 1.10. Here again, Lover directs away from the

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use of benzyl alcohol.

Clearly the above results direct one skilled in the art away from the use of benzyl alcohol as a pediculicide.

Concerning phenyl ethanol, this compound was 100% effective against lice when 100% alcohol was used. The present claims do not include the use of 100% alcohol, nor anywhere close to 100% alcohol.

In a 25% solution, effectiveness was 0%. The present compositions are highly effective at concentrations much below 25%.

It should further be noted that Lover's claims do not include phenyl ethanol, i.e. Lover does not include phenyl ethanol as an effective agent for controlling lice.

With respect to independent claims 1 and new claim 45, the limitations not taught or suggested by the Lover reference include the following:

1. The limitation in paragraph A)a) of a weight range of monohydric aralkyl alcohol of from 1 to 50%. Lover shows that even at 100% concentration benzyl alcohol is only 90% effective as a pediculicide. Applicant has shown extremely high effectiveness levels for the different compositions of the invention. See e.g. Example 15 on pages 24-27 where a composition containing only 5% by weight of benzyl alcohol (Example 1 composition) produced kill rates of greater than 99% against lice. See also example 16 on pages 27-30 where a composition of the invention also containing only 5% by weight of benzyl alcohol (Example 2 composition) produced a kill rate of 100% against lice.

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2. Subparagraph A)b) wherein the compositions are formulated to prevent the ectoparasites from obtaining air through their breathing apparatuses. It has been discovered that the combination of the pesticidal activity of the aralkyl alcohols of the invention when present in compositions that suffocate the ectoparasites provide very high kill rates (over 99%) in short contact times. The aralkyl alcohols have been found to prevent the ectoparasites from closing their breathing apparatuses (see e.g. page 6 lines 15-19), and this effect combined with the suffocating effect of compositions that prevent air from entering the ectoparasites' breathing apparatuses (spiracles in lice) results in these very high kill rates. There is of course no teaching or suggestion in Lover for the concept of using compositions that suffocate the ectoparasites (see e.g. col. 2 lines 25-30 where it is stated that "Any pharmaceutically acceptable carrier" can be used).
3. The limitation in subparagraph A)c) in where it is discovered that these very high kill rates are obtained when both the hair and skin in the infected areas are completely saturated with the compositions of the invention. Here again there is no such disclosure in the Lover reference and clearly not with respect to this limitation applied to the compositions of the present invention. With respect to this limitation a Declaration under 37 CFR § 132 is attached hereto proving the unexpected importance of this limitation.

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4. The limitation that the composition is free from any pesticidally active compounds other than the pesticidally active alcohol of the invention.
There is nothing in Lover that is directed to this limitation.

It should also be noted as stated above that the very short contact times of from 2 to 10 minutes are generally sufficient to achieve the above very high kill rates. See e.g. page 5, line 17 – page 6, line 2.

It should further be noted that the presently claimed compositions will function effectively even if the ectoparasites become resistant to the pesticidal activity of the monohydric aralkyl alcohols since they cannot become resistant to asphyxiation, which can provide a kill rate greater than 99%, and usually 100% (see page 10 lines 7-11). There is no such teaching or suggestion in the Lover reference that would lead to this concept.

It is also contended that Lover teaches away from the use of either benzyl alcohol or phenyl ethanol.

The U.S. Court of appeals for the Federal Circuit in In re Gurley, 31 USPQ 2d 1131 held that “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant.” See also In re Braat, 16 USPQ 2d 1812, where the CAFC held that one important indicium of nonobviousness is teaching away from a claimed invention in the prior art.

It is respectfully contended that Lover discourages one of ordinary skill from the

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use of benzyl alcohol and phenyl ethanol.

In summary, the Lover reference does not teach or suggest the following:

- a) air-impermeable compositions;
- b) in amount sufficient to prevent the ectoparasites from closing their breathing apparatus;
- c) leaving in place until the ectoparasites are killed;
- d) achieving very high kill rates in short periods of time;
- e) since the mechanism of action includes suffocation, the ectoparasites cannot develop resistance to the compositions, which can and does occur with toxic chemical pesticides;
- f) wherein the compositions are safe and effective and are free from pesticides other than any pesticidal action exhibited by the aralkyl alcohols; and
- g) the importance of complete saturation of the hair and skin in the infected areas.

It is well settled law that all limitations must be considered in considering obviousness under 35 U.S.C. 103; it is error to ignore specific limitations distinguishing over the references. See e.g. In re Boe and Duke (CCPA) 184 USPQ 38.

With respect to the Bassette reference, this reference discloses benzyl alcohol as one of a list of plant essential oils. A preferred embodiment is a mixture of benzyl alcohol and pyrethrins (see col. 3, lines 39-45).

In the test results given in Example 1., column 7, only benzyl alcohol in

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combination with pyrethrins (the latter being excluded from the present claims) gave “very good kill”. Other benzyl alcohol containing compositions (i.e. compositions G and H) were rated as less effective than compositions A-D, without any indication as to whether Kill or Repellancy was being measured.

Accordingly, the only composition where a Kill rating is given is composition A which is clearly excluded by the present claims (“free from pesticides other than any pesticidal activity provided by the at least one monohydric alcohol”).

In addition to the above, there is no disclosure in Bassette of:

- a) an air-impermeable composition;
- b) in amount sufficient to prevent the ectoparasites from closing their breathing apparatus;
- c) leaving the composition in contact with the skin and hair until the ectoparasites have been killed;
- d) achieving very high kill rates in short periods of time;
- e) since the mechanism of action include suffocation, the ectoparasites cannot develop resistance to the compositions, which can and does occur with toxic chemical pesticides;
- f) wherein the compositions are safe and effective and are free from pesticides other than any pesticidal action exhibited by the aralkyl alcohols; and
- g) the importance of complete saturation of the hair and skin in the infected areas.

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It is therefore respectfully contended that Bassette does not teach or suggest the presently claimed method.

Concerning the Cardin reference, this reference discloses ovicidal/pediculicidal anti-lice compositions containing quarternary ammonium salts, long chain fatty amines, and mixtures thereof with alkanol synergizers selected from phenyl C₂-C₆ alkanols, phenyl C₂-C₆ diols, and mixtures thereof.

The alkanols are never used alone, and their only disclosed function is to act as synergizers for the ammonium compounds and amines, which are the chemical pediculicides. See e.g. column 3, lines 21-22, where it is stated that "In the present invention, alkanol synergizers enhance the efficacy of the active compositions". (underlining added).

All of the present claims contains the limitation that no pesticides are present in the compositions used in the method of the invention other than any pesticidal activity provided by the monohydric aralkyl alcohols, hence excluding the compositions of Cardin, in which the ammonium compounds and amines are chemical pediculicides (see e.g. col. 3 above and col. 2, lines 43-45).

Cardin does not teach or suggest the following:

- a) air-impermeable compositions;
- b) in amount sufficient to prevent the ectoparasites from closing their breathing apparatus;
- c) leaving in place until the ectoparasites are killed;

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- d) achieving very high kill rates in short periods of time;
- e) since the mechanism of action includes suffocation, the ectoparasites cannot develop resistance to the compositions, which can and does occur with toxic chemical pesticides;
- f) wherein the compositions are safe and effective and are free from pesticides other than any pesticidal action exhibited by the aralkyl alcohols; and
- g) the importance of complete saturation of the skin and hair.

In addition, Cardin discloses only phenyl C₂-C₆ alkanols. Benzyl alcohol is a phenyl C₁ alkanol. Hence this reference is completely irrelevant with respect to new claims 45-63, which are all limited to benzyl alcohol.

It is therefore respectfully contended for the reasons given above that Cardin does not teach nor render obvious the presently claimed method.

With respect to the Pearlman reference, this reference is directed to driable pediculostatic agents that elicit an "immersion reflex" in lice to immobilize them. The pediculostatic agents are then dried to kill at least some of the lice. The driable pediculostatic agents used in Pearlman's invention are "surfactants, lipid materials and alkanols" (col. 10, lines 48-51). The alkanols within the scope of the invention are disclosed in col. 12, lines 52-65, and appear to be any "nonvolatile fatty alcohol".

Pearlman does not disclose any of items a) through g) disclosed above in discussion of the other references.

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Accordingly, the Pearlman reference is respectfully contended to contain no disclosures relevant to the presently claimed invention.

The Examiner is taking a driable unrelated pediculostatic agent from the Pearlman reference and combining this with the substantially ineffective compositions of the Lover, Bassette, and Cardin references all without any teaching or suggestion in any of these references to do so, and completely out of context, concluding that the present compositions and methods are thereby obtained, which is respectfully submitted to be incorrect for the reasons discussed above. This rejection is contended to be a hindsight rejection using the present invention as a template.

It is of course improper to rebuild references, in light of applicant's disclosure, in order for it to operate in a manner never intended or contemplated by the reference. Ex parte Garrett, POBA (1961) 132 USPQ 514. In order for a combination of references to render an invention obvious, it must be obvious that their teachings can be combined. In re Avery, 186 USPQ 161. The references, viewed by themselves and not in retrospect, must suggest doing what applicant has done. In re Schaffer (CCPA 1956) 108 USPQ 326, In re Skoll (CCPA 1975) 187 USPQ 481. The mere fact it is possible for two isolated disclosures to be combined does not render the result of that combination obvious absent a logical reason of record which justifies the combination. In re Regal et al. (CCPA 1975) 188 USPQ 136.

It is respectfully contended that the Examiner has not provided a sufficient basis upon which to conclude that one having ordinary skill in the art would have been led to modify the applied references to arrive at the claimed method. In re Newell, 891 F.2d

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899, 13 USPQ2d 1248 (Fed. Cir. 1989), In re Laskowski, 871 F.2d 115, 10 USPQ2d 1397 (Fed.Cir. 1989).

In addition, it is not apparent and the Examiner does not explain why the disclosed processes in the prior art would inherently (necessarily) yield the same product used in the present claims. In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986); In re Oelrich, 666 F.2d 578, 212 USPQ 323 (CCPA 1981); In re Wilking, 535 F.2d 631, 190 USPQ 59 (CCPA 1976).

There is data in the specification which reveals that products used in the claimed method exhibit properties (e.g. ability to suffocate ectoparasites) which are not exhibited by those prepared in accordance with any process disclosed in the references. The Examiner should give more consideration to this data in the specification. Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 5 USPQ2d 1434 (Fed. Cir. 1988); Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281.

The Examiner's attention is directed to operating Examples 1-14 where compositions containing benzyl alcohol are set forth, and Examples 15, 16, and 17 where the compositions of Examples 1, 2, 5, and 6 were evaluated clinically against lice, nymphs, and/or nits wherein each subject (lice infected) had two 10 minute treatments one week apart in Examples 15 and 16, resulting in 100% effectiveness; and Example 17 where a 10 minute treatment against nits resulted in ovicidal activity of 94.9% for the composition of Example 5 and 93.1% for the composition of Example 6.

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In the Office Action, the Examiner contends that the cited references show benzyl alcohol effective as a licide and ovicide at from 0.25-5% (Cardin), 10-40% (Lover), 0.01-95% (Bassette).

This contention is respectfully submitted to be incorrect, for all the reasons discussed above. For example, Lover shows benzyl alcohol as ineffective as a licide for all practical purposes. Cardin requires the presence of chemical amine and ammonium pediculicides and discloses certain alcohols as synergizers for the above chemical pediculicides. Bassette shows that only benzyl alcohol in combination with pyrethrins was effective.

In addition, the references do not disclose or suggest any of items a) through g) set forth above in discussions of individual references, i.e. none of the references, either singly or in combination, disclose a method for using compositions to kill ectoparasites in which:

- a) an air-impermeable composition;
- b) in amount sufficient to prevent the ectoparasites from closing their breathing apparatus;
- c) leaving the composition in contact with the skin and hair until the ectoparasites have been killed;
- d) achieving very high kill rates in short periods of time;
- e) since the mechanism of action include suffocation, the ectoparasites cannot develop resistance to the compositions, which can and does occur with toxic chemical pesticides;

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- f) wherein the compositions are safe and effective and are free from pesticides other than any pesticidal action exhibited by the aralkyl alcohols; and
- g) the importance of complete saturation of the hair and skin in the infected areas.

On page 8 of the Action, the Examiner states that the claims are broader than the scope argued and Lover is a directive for alcohol use for ectoparasite control.

However, the scope of the claims has been discussed herein, and as discussed above Lover does not direct for the use of aralkyl alcohols as effective pesticides. Also, as discussed above, Lover does not teach or suggest any of the claim limitations or advantages provided by the present invention.

On pages 7 and 8 of the Action the Examiner has rejected a number of the present claims for obviousness-type double patenting.

The rejections will be discussed below.

Concerning the rejection of claims 1-5, 8-13, 17-20, 22-33, and 39-44 for obviousness-type double patenting over claims 28, 29, and 31-38 of Patent No. 6,793,931, the above patented claims do not contain at least the following claim limitations of the above claims of the present application:

1. Effectiveness against ectoparasite nymphs and eggs as well as the ectoparasites themselves.
2. The quantity of aralkyl alcohol of from 1 to 50% by weight of the composition.

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3. The requirement of complete saturation of the hair and skin. The importance and unobviousness of this has been demonstrated in the 37 CFR § 132 Declaration included with this response.
4. Leaving the composition in contact with the infected skin and hair until most of the nymphs and eggs have been killed (as well as the ectoparasite).

Hence, it is respectfully submitted that the present claims are patentably distinct from those of the above patent.

Concerning copending application 10/382,188, the limitations in the present claims not present in the claims of the above copending application include the following:

1. Effectiveness against nymphs as well as the ectoparasites and their eggs.
2. The requirement of complete saturation of the hair and skin. See attached 132 Declaration showing the importance and unobviousness of this limitation.
3. Leaving the composition in contact with the infected skin and hair until most of the nymphs and eggs have been killed.

Hence, it is respectfully submitted that the present claims are in fact patentable over those in copending application 10/382,188.

Concerning copending application 10/336,457, the limitations in the present claims not present in the claims of the above copending application are as follows:

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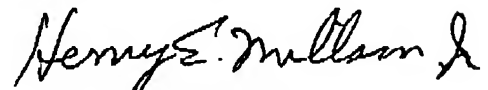
1. Effectiveness against ectoparasite nymphs and their eggs as well as the ectoparasites themselves.
2. The requirement of complete saturation of the hair and skin. The importance and unobviousness of this has been demonstrated in the 37 CFR § 132 Declaration included with this response.
3. Leaving the composition in contact with the infected skin and hair until most of the nymphs and eggs have been killed (as well as the ectoparasites).

Hence, it is respectfully submitted that the present claims are patentably distinct from those of the above copending application.

Hence, it is respectfully submitted that the present claims are in fact patentably distinct from the claims of U.S. 6,793,931 and the above copending applications.

In view of the amendments to the claims and the above discussion, allowance of claims 1, 3-9, 11, 13, 15, 16, 18, 20-26, 33-36, and 45-63 as amended is respectfully solicited.

Respectfully submitted,



Henry E. Millson, Jr.
Reg. No. 18,980
675 Golden Hawk Drive
Prescott, AZ 86301
phone and fax (928)445-2453